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Introduction

The overarching aim of this study is to describe the epidemiology, natural history, and prognostic predictors of mild traumatic brain injury (mTBI) in a well-defined cohort of recently-deployed soldiers at Fort Carson and Fort Bragg. This study will augment the ongoing surveillance and clinical efforts at these locations by expanding the post-deployment assessment of traumatic brain injury (TBI) and TBI-related exposures; identifying pre-existing and deployment-related exposures and comorbid conditions that may influence the risk or prognosis of mTBI-related sequelae; and re-assessing this cohort at three, six, and twelve months after return from deployment with the aim of determining the persistence of post-deployment symptoms and the degree to which these symptoms impact on military or civilian employment, including fitness for military duty, functional status, and quality of life.

Body

Award W81XWH-08-2-0105 was issued to the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF), effective 1 May 2008. The protocol review process was completed for Fort Carson, and is in its final stages for Fort Bragg. The Fort Carson site successfully recruited 189 subjects beginning 24 August 2009, and recruited a second wave of 189 subjects in May/June 2010. The Qualitative Sub-study has recruited a total of 103 subjects over the two recruitment cycles. The protocol for the Fort Bragg study site was approved by the WAMC IRB and CIRO on 22 April 2009. HJF signed a CRADA with CIRO on 12 May 2009 for the WAMC protocol. Final approval to start the study at Fort Bragg was placed on hold due to reassignment of the PI to another Army MTF. The new PI has reviewed the protocol and is finalizing it for resubmission to the WAMC IRB. The protocol for the Fort Carson study site was approved by the BAMC IRB on 1 April 2009 contingent upon minor clarifications. These clarifications have been made and the protocol has been resubmitted to the BAMC IRB for review by CIRO.

Key Accomplishments

- All Quarterly Reports submitted on schedule, per (award) terms and conditions.
- Protocol for the Fort Bragg study site approved by local IRB and CIRO on 22 April 2009. Protocol on hold until new PI identified. Protocol has been revised to accommodate modifications made at Fort Carson and PI is finalizing it for resubmission.
- Protocol for the Fort Carson study site approved by local IRB on 1 April 2009. Local IRB transferred to MAMC, approval obtained after IRB, HJF, and CIRO reviews. Protocol deviations reported and reviewed, and study received approval to continue recruitment in time for second recruitment wave.
- 169 subjects from the first wave of subject recruitment continue to be followed by phone for the study (20 have been lost to follow-up or declined further follow-ups); 188 of the 189 subjects from the second wave of subject recruitment will be contacted for the first follow-ups shortly (1 subject has withdrawn from consent).

Reportable Outcomes

No research findings are available at this time.

Conclusion

The following is a summary of key administrative/management actions during the reporting period:

- Award W81XWH-08-2-0105 issued to HJF, effective 1 May 2008.
- Staff required for the study at Fort Bragg have been hired and trained. Additional staff will be recruited before the first recruitment of subjects begin.
- Staff required for the study at Fort Carson have been hired and trained.

References

N/A at this time

Appendices

N/A at this time

Supporting Data

N/A at this time